REMARKS

Claims 22-57 presently appear in this case. No claims have been allowed. The present amendment is being made in order to supplement applicant's amendment of March 12, 2004, and in light of a telephone conference with Examiner Cook on September 20, 2004. Consideration of the present supplemental amendment in conjunction with applicant's amendment of March 11, 2004, and reconsideration and allowance are hereby respectfully urged.

In an examiner-initiated telephone conference on September 20, 2004, the examiner indicated that she was considering withdrawing the rejection over the Amgen patent if applicant would be willing to amend claim 37 to specify at the end "and wherein the interferon does not enter the bloodstream." The examiner stated that this was part of applicant's arguments, and applicant's previous response pointed out where this language was supported in the specification. The examiner stated, however, that she had not been convinced to withdraw the rejection over Eby for claim 36 and those claims dependent therefrom. The examiner states that Eby comprehends the amount claimed if the patient is small, and that Eby does not say nasal administration is totally ineffective, but is only poorly effective. Thus, the examiner still considers Eby to anticipate. The examiner suggested that the case might be in condition for allowance if claim 37 were amended as suggested, and claim 36 and those claims dependent therefrom were deleted.

Applicant cannot accept the examiner's proposal, as applicant strongly disagrees that Eby is an anticipation of claim 36. However, applicant is in agreement with amending claim 37 as suggested by the examiner in order to obviate all of the rejections other than the rejection over Eby. Accordingly, by this amendment claim 37 has been amended as suggested by the examiner, and the same language is inserted into claim 36 in order to avoid any rejection of claim 36 over Amgen. The present amendment should now limit the outstanding issues only to that of anticipation over Eby.

New claims 52-57 have now been added, directed to a treatment of a viral infection other than rhinovirus. As the disclosure of Eby relates only to rhinovirus, it cannot anticipate the new claims, and these claims must be considered to be allowable for reasons similar to the finding of allowability of claim 37.

It is respectfully requested that the examiner reconsider her refusal to withdraw the rejection based on Eby for the following reasons. It is well established that to anticipate a claim, a reference must teach every element of the claim. See MPEP §2131. A reference is good only for that which it clearly and definitely discloses. See *In re Hughes*, 145 USPQ 467, 471 (CCPA 1965) and *In re Moreton*, 129 USPQ 227, 230 (CCPA 1961). An ambiguous reference will not support an anticipation rejection. See *In re Hughes, supra*, and *In re Turlay*, 134 USPQ 355, 360 (CCPA 1962). Here, Eby does not

clearly and unambiguously disclose every element of present claim 36.

Claim 36 is directed to a method for treating a viral infection by administering "an effective amount" of interferon, which effective amount is greater than 20 x 10^6 IU for a 70 kg human. The administration is via oromucosal contact. Eby states, at column 5, lines 31-42:

> [T]he reason all antiviral agents, antirhinoviral agents, interferons, interferon inducers, T-cell mitogens, decongestants, drying agents, astringents, antihistamines, antibradikinins, protein precipitators, and all other pharmaceutical agents suitable for shortening the duration of common colds or generally treating common colds fail, or produce limited results is because ... they are applied to the more logical and more obvious treatment locus, the interior of the nose, or by a secondary route such as oral ingestion or by injection. [emphasis added]

This is not a clear and unambiguous disclosure that, from among all of the agents taught, a specific one, interferon, has previously been administered oromucosally to the interior of the nose in an effective amount. Interferon, as one of all pharmaceutical agents suitable for treating or shortening the duration of common colds, may have been previously administered only by oral ingestion or by injection. There is no clear teaching in Eby that interferon has ever been administered oromucosally to the interior of the nose to anyone in any amount. Eby may have been referring to one or

the other of the long list of pharmaceutical agents when referring to failure or limited results when administering nasally.

Furthermore, there is no disclosure in Eby that any "effective amount" exists for the administration of interferon oromucosally to the interior of the nose, because Eby teaches that, in general, all such procedures either fail or produce limited results. The reference is ambiguous as to whether administration of interferon to the interior of the nose fails, or whether it produces limited results. If it fails, certainly no effective amount is disclosed. The present claims require an effective amount. To the extent that Eby is not clear whether any such administration may fail or may give limited results, the patent is ambiguous and thus cannot serve to anticipate.

The disclosure at column 3, lines 35-41, of Eby discloses substantially the same thing as in the above-quoted portion of column 5. The disclosure that nasal administration, injection or swallowing "produced poor results" is the same as the disclosure in column 5 that they fail. Thus, when Eby, talking about the prior art, states that any one of a large number of agents, one of which is interferon, may have been either applied to nasal tissues, injected, or orally administered by swallowing in the past, it

is not clear, definite and unambiguous that all of the specified agents have been applied in all of those different ways in the past. Furthermore, it is apparent that not all of these agents when applied in these various ways can be administered in an effective amount, because they are disclosed as failing or producing poor results. The term "produce poor results" does not mean that there is some degree of effectiveness. "Poor results" can only be interpreted as ineffective or worse.

The examiner's attention is invited to the recent Federal Circuit case of *Trintec Industries Inc. v Top-U.S.A. Corp.*, 63 USPQ2d 1597, 1600 (Fed Cir 2002), which states that "strict identity" is required in the test for novelty (holding that the disclosure of a printer does not anticipate a claim that requires a photocopier). Because of the strict identity required for the test of novelty, and because nothing in the Eby discussion of the prior art clearly, definitely and unambiguously discloses that interferon has ever been administered by oromucosally applying an effective amount of interferon to the nasal tissues, there can be no anticipation. Furthermore, the present claim language would not be obvious, because the reference teaches away from doing so. Everything that the reference positively teaches has been disclaimed in claim 36. For all of these reasons, reconsideration and

withdrawal of the rejection over Eby is also respectfully urged.

The examiner's attention is invited to patent no. 6,361,769 to the present inventor. In the prosecution of that patent before Examiner Andres, a rejection over Eby was overcome with substantially the same proviso added to the claims as appears herein. There is no anticipation here for the same reason that the examiner agreed there was no anticipation over Eby in the prosecution of the application that led to patent 6,361,769. Other related patents to the present inventor are 5,997,858, 6,207,145 and 6,660,258.

Accordingly, consideration of the present supplemental amendment in conjunction with applicant's amendment of March 11, 2004, reconsideration and withdrawal of the prior rejections, and allowance are earnestly solicited.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.
Attorneys for Applicant(s)

By
Roger L. Browdy
Registration No. 25618

RLB:jab
Telephone No.: (202) 628-5197
Facsimile No.: (202) 737-3528

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CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this supplemental amendment is being facsimile transmitted to the Patent and Trademark Office, on the date shown below.

Jonathan Brammer

Name

JC B

Signature

October 4, 2004

Date